Chapter 8: Institutional Controls in Baseline Risk Assessments

8.1 Introduction

Institutional controls are remedial alternatives "which limit human activities at or near facilities, to protect health and the environment and assure continued effectiveness of the program" (USEPA, 1990). Examples of institutional controls include land and resource use and deed restrictions, provisions for alternative water supplies, and well-drilling prohibitions (USEPA, 1990).

The EPA states in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) (USEPA, 1990) that institutional controls are considered "limited action alternatives," and that baseline risk assessments are not the "proper place to take institutional controls into account, " There are instances, however, where institutional controls are not precluded from being described and/or factored into alternative exposure scenarios. This chapter provides an overview of how the use of institutional controls have been considered in CERCLA activities

8.2 Discussion of Institutional Controls in Statutes, Regulations, and Guidelines

8.2.1 Statutes

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980 [42 U.S.C. 9601], and the Superfund Amendments and Reauthorization Act (SARA) of 1986, passed by the U.S. Congress, are the statutes that establish the broadly defined goal of reducing and mitigating human exposures to hazardous wastes. Section 121 of CERCLA, Clean-up Standards, indicates a strong preference for the selection of cost-effective permanent remedial alternatives. CERCLA defines "removal" as the cleanup or removal of released hazardous substances from the environment; actions taken in the event of the threat of release of hazardous substances; actions to monitor, assess, and evaluate the release of hazardous substances; the disposal of removed material; and other actions to prevent, minimize, or mitigate damage to public health or to the environment [42 USC 9601 et. seq.]. In addition, CERCLA indicates that the term "removal" also includes "security fencing or other measures to limit access" (CERCLA, Sections 101-23 and 101-24).

8.2.2 Regulations

CERCLA statutes are implemented by regulations contained in the NCP of 1985 and its revisions in 1990 (USEPA, 1985; 1990). The NCP requires that a Remedial Investigation and Feasibility Study (RI/FS) be conducted at CERCLA sites, and that the RI/FS assess the "baseline risk posed by the contaminants under investigation" (USEPA, 1990) .

EPA indicates that institutional controls are "a necessary supplement when some waste is left in place," although they "should not substitute for more active response measures that actually reduce, minimize, or eliminate contamination (USEPA, 1990). Examples of institutional controls include land and resource use and deed restrictions, well-drilling prohibitions, and provisions for an alternative water

supply (USEPA, 1990). Section 300.430(a)(l) of the 1990 NCP directs the development of alternatives based on engineering controls, and "as necessary institutional controls, which limit human activities at or near facilities, to protect health and environment, " The preamble to the 1990 NCP explained that "institutional controls may be used as a supplement to engineering controls over time but should not substitute for active response measures as the sole remedy unless active response measures are not practicable" (USEPA, 1988).

In response to comments on the purpose of risk assessments, EPA clarified in the 1990 NCP that a risk assessment "provides a consistent process for evaluating and documenting threats to human health and the environment posed by hazardous material at sites." EPA also stated in the same document that the objectives of the risk assessment are to:

1. provide an analysis of baseline risk (i.e., the risks that exist if no remediation or institutional controls are applied to a site) and

2. use the risks and exposure pathways developed in the baseline risk assessment to target chemical concentrations associated with levels of risk that will be adequately protective of human health for a particular site (i.e., remediation goals).

8.2.3 Guidelines

The human health evaluation process was delineated initially in the Superfund Public Health Evaluation Manual (SPHEM) (USEPA, 1986), and later revised and published as Risk Assessment Guidance for Superfund (RAGS) (USEPA, 1989). The baseline risk assessment is defined as "an analysis of the potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action)." RAGS further states that baseline risks are "risks that might exist if no remediation or institutional controls were applied at a site" (USEPA, 1989). The use of institutional controls in CERCLA risk assessments is addressed in RAGS Part B, Development of Risk-Based Preliminary Remediation Goals (PRGs) (USEPA, 1991a), and in RAGS Part C, Risk Evaluation of Remedial Alternatives (USEPA, 199 lb). RAGS Part B provides guidance on using toxicity values and exposure information to derive risk-based PRGs. PRGs are the standards that the remedial alternatives must meet to achieve the criteria set forth in Section 300.430(e)(9)(iii) of the NCP. According to RAGS Part B, the calculation of PRGs involves identifying the most appropriate future land use for the site, which may become complicated because the assumptions for the site may be different from the land use in the surrounding area. For example, RAGS Part B discusses waste managed on site in a residential area, stating that PRGs for groundwater are based on residential exposures, and the PRGs for soils are based on industrial land use "with some management or institutional controls" (USEPA 1991a). RAGS Part C provides assistance on using risk information to evaluate (1) remedial alternatives during the FS and (2) the selected remedial alternative during and after its implementation. RAGS Part C specifically notes that if a remedial alternative relies on institutional controls "to reduce or eliminate exposure to contaminated media, then the ability of these controls to maintain protectiveness should be considered" (USEPA 1991 b). RAGS Part C also remarks that for sites where institutional controls are employed "the concentrations of chemicals

in a contaminated medium may remain the same as the baseline concentrations. The risk will have been reduced or eliminated however, by mitigation or elimination of the exposure pathway" (USEPA, 199lc).

8.3 Issues and Regulator Dialogue

8.3.1 Institutional Controls Issues

The NCP indicates that in instances where the balancing of trade-offs among remedial alternatives results in no practicable engineering remediation (e.g., treatment, removal, capping), institutional controls may be the selected remedial activity. Paragraph 300.68(i) of the NCP specifies that "the appropriate extent of remedy will be determined by the lead agency's selection of a cost-effective remedial alternative that. effectively mitigates and minimizes threats to, and provides adequate protection of public health and welfare and the environment" (USEPA, 1990). Although Sic-specific institutional controls may ultimately be the selected remedial action, there are incongruent policies on how they maybe addressed in baseline risk assessments. The following issues have been identified:

Evaluation of Institutional Controls

EPA responded to comments made on performing baseline risk assessments assuming that institutional controls were in place and effective at preventing exposure. The Agency indicated in the 1990 NCP that the baseline risk assessment is not the "proper place to take institutional controls into account" (see also USDOE, 1992). According to EPA, the proper place to take institutional controls into account is in the process outlined in RAGS Part C, Risk Evaluation of Remedial Alternatives. RAGS Part C indicates that mitigation or elimination of the exposure pathway may reduce or eliminate the risk from a contamination source where the contaminant concentration has remained the same (USEPA, 199lb).

Institutional Controls in Exposure Scenario Development

Exposure assessment includes the characterization of a site with respect to its physical characteristics as well as those of the human populations (USEPA, 1986). An exposure scenario includes facts, data, assumptions and professional judgments about how exposure takes place. According to Guidelines for Exposure Assessment (USEPA, 1992), the development of exposure scenarios addresses the following:

- Exposure Setting - The physical setting where exposure takes place.
- Exposure Pathways - The pathway from source to exposed population.
- Chemical Characterization - The amounts, locations, environmental, fate, environmental pathways, variation of concentration with time, etc.

- Population Characterization - Identification of exposed populations, and the profile of contact with a chemical based on behavior, location as a function of time, characteristics of the population, etc.

The NCP states that "EPA encourages the taking of early actions, under removal or remedial authority, to abate the immediate threat to human health and the environment" and that these actions are "prior to or concurrent with conduct of an RI/FS" (USEPA, 1990). The NCP also states that "a completed baseline risk assessment generally will not be available or necessary to justify an interim action." Given the dynamic nature of CERCLA activities, and in spite of a constant striving to separate risk analysis from risk management, baseline risk assessments often need to look at the accomplishments of early actions: "Has the contaminated soil been removed from the site?""Are the underground storage tanks still in place?" "Is the security fencing preventing trespassers from contacting the site contaminants?" The answers to these and other questions are inevitably factored into the development of exposure scenarios, and, although institutional controls constitute risk management decisions, it would seem appropriate that the baseline risk assessment could indicate through the use of alternative exposure scenarios the existence of early actions that, according to the NCP "abate the immediate threat to human health and the environment" (USEPA, 1990).

Institutional Controls in Land Use Determination

Characterizing the human population involves determining current and future land use. There are instances where CERCLA sites are categorized as industrial and/or located in areas sensitive to national security (e.g., Department of Energy's laboratories). In these instances, exposure scenarios are often based on occupational exposure profiles (e.g., 8-hour days, 5 days/week, etc.). Realistically assessing the completeness of an exposure pathway at sites where institutional controls are in place (e.g., 24-hour patrolled and fenced area) may result in the exclusion of, for example, dermal contact with contaminated soil by children, although it may include contact to on-site contaminated groundwater if there is potential for current or future contaminant movement off site. Regarding the estimation of high-end exposure intakes, the Exposure Assessment Guidelines state that "the estimate is by definition intended to fall on the actual (or in the case of future exposures, probable) exposure distribution" (USEPA, 1992).

In determining future land use, RAGS recommends making the most conservative choice (i.e., residential land use). However, RAGS also mentions that "an assumption of future residential land use may not be justifiable if the probability y that the site will support residential use in the future is exceedingly small" (USEPA, 1989). The 1990 NCP also states that "the assumption of residential land use is not a requirement of the program but rather is an assumption that may be made, based on conservative but realistic exposures, to ensure that remedies that are ultimately selected for the site will be protective" (USEPA, 1990). The use of professional judgment during the determination of future land use is seen by RAGS as "critical," and it recommends 1) consulting the remedial project manager and 2) supporting the selection of alternative land use with a "logical reasonable argument" (USEPA, 1989).

"Reasonableness" is discussed in RAGS and the 1990 NCP under the concept of reasonable maximum exposures (RME) as applied to assumptions made during the assessment of human health risks: "RME is the maximum exposure that is reasonably expected to occur at a site" (USEPA, 1989; 1990).

Thus, at CERCLA sites located at non-residential DOE facilities, where a change in land use in the foreseeable future is unlikely, it may be reasonable to assume that future land use will be the same as current use (i.e., non-residential).

The results of the baseline risk assessment will help establish acceptable exposure levels for use in developing remedial alternatives "Exposure estimates for future use of the site will provide the basis for the development of protective exposure levels" (USEPA, 1990). According to EPA, if the future land use is unclear, "risks assuming residential land use can be compared to risks associated with other land uses, such as industrial" (USEPA, 1990). RAGS Part B states that in the absence of site-specific information to select one future land use over another, "it may be appropriate to develop a separate set of risk-based PRGs for each possible land use" (USEPA, 199la).

8.3.2 Regulator Dialogue

In conclusion, EPA currently directs that the effectiveness of institutional controls not be evaluated during CERCLA baseline risk assessments, but under the authority of RAGS Part C, Risk Evaluation of Remedial Alternatives. However, language in the NCP would appear to indicate that institutional controls could be addressed in a baseline risk assessment as part of the development of current and future exposure scenarios. In such scenarios, land-use patterns may preclude the completeness of an exposure pathway (e.g., 24-hour patrolled and fenced area). EPA states that exposure scenarios as part of a baseline risk assessment "provide a powerful tool to evaluate the potential reduction of exposure and risk for these various options, and consequent y are quite useful in many cost-benefit analyses" (USEPA, 1992). EPA also adds that "well-crafted and soundly based exposure scenarios may also help communicate risks and possible options to community groups" (USEPA, 1992).

8.4 References

Defense Cleanup. 1993. Volume 4, Number 6; ISSN: 0083-9735. February 12, 1993.

USDOE. 1992. Use of Institutional Controls in a CERCLA Baseline Risk Assessment. U.S. Department of Energy, Office of Environmental Guidance. Washington, D.C. EH-231-014/1292.

USEPA. 1985. National Oil and Hazardous Substances Pollution Contingency Plan. U.S. Environmental Protection Agency. [50 FR 47912].

USEPA. 1986. Superfund Public Health Evaluation Manual. U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. Washington, D.C. EPA 540/1-86/060.

USEPA. 1988. Reposed Revisions to the National Oil and Hazardous Substances Pollution Contingency Plan. U.S. Environmental Protection Agency. [53 FR 51423].

USEPA. 1989. Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A). U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. Washington, D.C. EPA 540/1-89/002.

USEPA. 1990. National Oil and Hazardous Substances Pollution Contingency Plan. U.S. Environmental Protection Agency. Washington, D.C. [55 FR 8666].

USEPA. 199la. Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals). U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. Washington, D.C. OSWER Directive 9285.7-01B, December 1991. NTIS #PB 92-963334.

USEPA. 199lb. Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part C, Risk Evaluation of Remedial Alternatives). U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. Washington, D.C. OSWER Directive 9285.7-0IC. NTIS #PB 92-963334.

USEPA. 1992. Guidelines for Exposure Assessment. U.S. Environmental Protection Agency. Washington, D.C. [57 FR 22888].